

Claims

What is claimed is:

1. A therapeutic pharmaceutical composition comprising

(a) an analgesic;

5 (b) a gel forming polymer;

(c) a nasal tissue irritant; and

(d) an emetic in sufficient amount to cause emesis if greater than a prescribed amount
of the analgesic of the therapeutic composition is ingested.

10 2. The therapeutic pharmaceutical composition of claim 1, wherein the pharmaceutical
composition is in unit dose form.

3. The therapeutic pharmaceutical composition of claim 1, wherein the pharmaceutical
composition is in a suppository, capsule, caplet, pill, gel, soft gelatin capsule, or compressed
15 tablet form.

4. The therapeutic pharmaceutical composition of claim 1, wherein the analgesic
comprises an opioid analgesic present in an amount of about 5 mg to about 200 mg on a solid
weight basis.

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5. The therapeutic pharmaceutical composition of claim 1, wherein the analgesic
comprises hydrocodone or a therapeutically acceptable salt thereof.

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6. The therapeutic pharmaceutical composition of claim 1, wherein the analgesic
comprises oxycodone or a therapeutically acceptable salt thereof.

7. The therapeutic pharmaceutical composition of claim 1, wherein the analgesic
comprises morphine or a therapeutically acceptable salt thereof.

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8. The therapeutic pharmaceutical composition of claim 1, wherein the analgesic is
selected from the group consisting of alfentanil, amphetamines, buprenorphine, butorphanol,
carfentanil, codeine, dezocine, diacetylmorphine, dihydrocodeine, dihydromorphine,

diphenoxylate, diprenorphine, etorphine, fentanyl, hydrocodone, hydromorphone, β -hydroxy-
3-methylfentanyl, levo- α -acetylmethadol, levorphanol, lofentanil, meperidine, methadone,
methylphenidate, morphine, nalbuphine, nalmefene, o-methylnaltrexone, naloxone,
naltrexone, oxycodone, oxymorphone, pentazocine, pethidine, propoxyphene, remifentanil,
5 sufentanil, tilidine and tramadol, or therapeutically acceptable salts thereof.

9. The therapeutic composition of claim 1, wherein the gel forming polymer comprises
one or more of polyethylene oxide having average molecular weight ranging from about
300,000 to about 5,000,000, polyvinyl alcohol having a molecular weight of about 20,000 to
10 200,000, hydroxypropyl methyl cellulose having a molecular weight of about 10,000 to
1,500,000, and a carbomer having a molecular weight ranging of about 700,000 to
4,000,000,000.

10. The therapeutic composition of claim 1, wherein the gel forming polymer comprises
15 one or more of polyethylene oxide having a viscosity in the range from about 8,800 to about
17,600 cps., polyvinyl alcohol having a viscosity in the range from about 4 to about 65 cps.,
hydroxypropyl methyl cellulose having a viscosity in the range from about 3600 to about
5600 cps., and a carbomer having a viscosity in the range from about 4000 to about 39,400
cps.

20 11. The therapeutic composition of claim 1, wherein the gel forming polymer comprises
polyvinyl alcohol.

12. The therapeutic composition of claim 1, wherein the gel forming polymer comprises
25 hydroxypropyl methyl cellulose.

13. The therapeutic composition of claim 1, wherein the gel forming polymer comprises
polyethylene oxide.

30 14. The therapeutic composition of claim 1, wherein the nasal tissue irritating amount of
a surfactant includes 1 to 5 percent by weight of one or more of poloxamer, sorbitan
monoesters, glyceryl monooleates and sodium lauryl sulfate.

15. The therapeutic composition of claim 1, wherein the nasal tissue irritating amount of a surfactant includes 1 to 5 percent by weight sodium lauryl sulfate.

5 16. The therapeutic composition of claim 1, wherein the emetic comprises zinc sulfate at about 5 to 25 percent by weight on a solid basis.

17. A method of making a therapeutic composition suitable for deterring drug abuse comprising

10 (a) providing an drug, a gel forming polymer having a viscosity, a nasal tissue irritant and emetic;

 (b) controlling the molecular weight or viscosity of the gel forming polymer;

 (c) controlling the amount of nasal tissue irritant such that nasal tissue irritation occurs if inhaled;

15 (d) controlling the amount of emetic such that emesis ensues only if more than a prescribed amount of the drug is consumed; and

 (e) combining the analgesic, gel forming polymer, nasal tissue irritant and emetic to form a therapeutic composition;

 wherein the composition deters abuse of the analgesic by forming a viscous gel upon contact with a solvent; inducing nasal irritation if inhaled, and inducing emesis if more than a prescribed amount of the analgesic is consumed.

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18. The method of claim 17, further comprising the step of processing the composition into a unit dose form.

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19. The method of claim 17, further comprising the step of processing the composition into a suppository, capsule, caplet, pill, or a direct compressed tablet form.

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20. The method of claim 17, wherein the drug comprises an opioid analgesic.

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21. The method of claim 17, wherein the drug is selected from the group consisting of alfentanil, amphetamines, buprenorphine, butorphanol, carfentanil, codeine, dezocine, diacetylmorphine, dihydrocodeine, dihydromorphine, diphenoxylate, diprenorphine,

etorphine, fentanyl, hydrocodone, hydromorphone, β -hydroxy-3-methylfentanyl, levo- α -acetylmethadol, levorphanol, lofentanil, meperidine, methadone, methylphenidate, morphine, nalbuphine, nalmefene, o-methylnaltrexone, naloxone, naltrexone, oxycodone, oxymorphone, pentazocine, pethidine, propoxyphene, remifentanil, sufentanil, tilidine and
5 tramadol, or therapeutically acceptable salts thereof.

22. The method of claim 17, wherein the drug comprises hydrocodone or a therapeutically acceptable salt thereof.

10 23. The method of claim 17, wherein the drug comprises oxycodone or a therapeutically acceptable salt thereof.

24. The method of claim 17, wherein the drug comprises morphine or a therapeutically acceptable salt thereof.

15 25. The method of claim 17, wherein the gel forming polymer comprises one or more of polyethylene oxide having average molecular weight ranging from about 300,000 to about 5,000,000, polyvinyl alcohol having a molecular weight of about 20,000 to 200,000, hydroxypropyl methyl cellulose having a molecular weight of about 10,000 to 1,500,000, and
20 a carbomer having a molecular weight ranging of about 700,000 to 4,000,000,000.

26. The method of claim 17, wherein the gel forming polymer comprises one or more of polyethylene oxide having a viscosity in the range from about 8,800 to about 17,600 cps., polyvinyl alcohol having a viscosity in the range from about 4 to about 65 cps.,
25 hydroxypropyl methyl cellulose having a viscosity in the range from about 3600 to about 5600 cps., and a carbomer having a viscosity in the range from about 4000 to about 39,400 cps.

30 27. The method of claim 17, wherein the step of controlling the amount of nasal tissue irritant comprises the step of adding 1 to 5 percent by weight of one or more of poloxamer, sorbitan monoesters, glyceryl monooleates and sodium lauryl sulfate.

28. The method of claim 17, wherein the gel forming polymer comprises polyvinyl alcohol.

29. The method of claim 17, wherein the gel forming polymer comprises hydroxypropyl 5 methyl cellulose.

30. The method of claim 17, wherein the gel forming polymer comprises polyethylene oxide.

10 31. The method of claim 17, wherein the step of controlling the amount of nasal tissue irritant comprises the step of adding 1 to 5 percent by weight sodium lauryl sulfate.

32. The therapeutic composition of claim 1, wherein the emetic comprises zinc sulfate at about 5 to 25 percent by weight on a solid basis.

15 33. A therapeutic pharmaceutical composition in unit dose form comprising
(a) an opioid analgesic;
(b) a gel forming polymer comprising one or more of polyethylene oxide having average molecular weight ranging from about 300,000 to about 5,000,000, polyvinyl alcohol 20 having a molecular weight of about 20,000 to 200,000, hydroxypropyl methyl cellulose having a molecular weight of about 10,000 to 1,500,000, and a carbomer having a molecular weight ranging of about 700,000 to 4,000,000,000;
(c) 1 to 5 percent by weight sodium lauryl sulfate; and
(d) less than about 0.6 to 2.0 gm of zinc sulfate.

25 34. The therapeutic pharmaceutical composition in unit dose form of claim 33, wherein the analgesic is selected from the group consisting of alfentanil, amphetamines, buprenorphine, butorphanol, carfentanil, codeine, dezocine, diacetylmorphine, dihydrocodeine, dihydromorphine, diphenoxylate, diprenorphine, etorphine, fentanyl, 30 hydrocodone, hydromorphone, β-hydroxy-3-methylfentanyl, levo-α-acetylmethadol, levorphanol, lofentanil, meperidine, methadone, methylphenidate, morphine, nalbuphine, nalmefene, o-methylnaltrexone, naloxone, naltrexone, oxycodone, oxymorphone,

pentazocine, pethidine, propoxyphene, remifentanil, sufentanil, tilidine and tramadol, or therapeutically acceptable salts thereof.

35. The therapeutic pharmaceutical composition of claim 33, wherein the analgesic
5 comprises hydrocodone or a therapeutically acceptable salt thereof.

36. The therapeutic pharmaceutical composition of claim 33, wherein the analgesic
comprises oxycodone or a therapeutically acceptable salt thereof.

10 37. The therapeutic pharmaceutical composition of claim 33, wherein the analgesic
comprises morphine or a therapeutically acceptable salt thereof.

38. A therapeutic pharmaceutical composition comprising
(a) an analgesic;
15 (b) a gel forming polymer;
(c) a mucosal tissue irritant; and
(d) an emetic in sufficient amount to cause emesis if greater than a prescribed amount
of the analgesic of the therapeutic composition is ingested.

20 39. The therapeutic pharmaceutical composition of claim 38, wherein the analgesic
comprises hydrocodone or a therapeutically acceptable salt thereof.

40. The therapeutic pharmaceutical composition of claim 38, wherein the analgesic
comprises oxycodone or a therapeutically acceptable salt thereof.

25 41. The therapeutic pharmaceutical composition of claim 38, wherein the analgesic
comprises morphine or a therapeutically acceptable salt thereof.

42. The therapeutic pharmaceutical composition of claim 1, wherein the nasal tissue
30 irritant comprises a surfactant.

43. The therapeutic pharmaceutical composition of claim 38, wherein the mucosal tissue
irritant comprises a surfactant.